

**REMARKS**

In the Office Action mailed July 30, 2007, claims 50-60, 62-107, and 142-149 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,094,598 to Elsberry et al.; claim 60 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Elsberry et al. in view of U.S. Patent No. 6,731,964 to Shenoy et al.; and claims 86, 88 and 108 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Elsberry et al. in view of U.S. Patent Publication No. 2003/0139778 to Fischell et al.

Applicants respectfully traverse the 35 U.S.C. § 102(b) rejection of claims 50-60, 62-107, and 142-149 as being anticipated by Elsberry et al. for at least the reason that Elsberry et al. fails to disclose every claim element. For example, independent claim 50, from which claims 51-60 and 62-107 ultimately depend, recites a system for treating a body including, among other things, a first processor connected to a sensor for processing detected electrical signals to generate a first control signal; a device configured to receive the first control signal and be controlled by the first control signal; and a second processor configured to generate a second control signal based on a monitored parameter of the device and to provide information relating to delivery of an agent to the body based on the second control signal. Elsberry et al. fails to disclose, at least, a second processor configured to generate a second control signal *based on a monitored parameter of the device*.

In the Office Action, the Examiner asserts that sensor (130), microprocessor (100), device (10), and analog-to-digital converter (140) of the Elsberry et al. system

respectively correspond to the claimed sensor, first processor, device, and second processor recited in Applicants' independent claim 50. The Examiner further asserts that the analog-to-digital converter (140) of Elsberry et al. is "configured to generate a second signal based on a monitored parameter of *the sensor* to a first (10) and second device (16)." (Office Action dated July 30, 2007 at page 2; emphasis added.) Elsberry et al. fails, however, to disclose a second processor configured to generate a second control signal based on a monitored parameter of *the device*.

Elsberry et al. discloses that sensor (130) monitors nerve cell activity and provides the monitored data to analog-to-digital converter (140), which converts the monitored data to a digital output signal. Based on the output signal of analog-to-digital converter (140), microprocessor (100) of drug delivery device (10) selects a drug dose and time interval for delivering the drug to a patient. (See Elsberry et al. col. 5, lines 1-65 and Fig. 3.) However, neither analog-to-digital converter (140) nor microprocessor (100) generates a control signal based on *a monitored parameter of device (10)*, as recited in Applicants' independent claim 50. Instead, microprocessor (100) bases its signal on the output of converter (140), which receives monitored nerve cell activity data from sensor (130).

The Examiner does not cite any disclosure of Elserry et al. for a teaching that analog-to-digital converter (140) bases its signal on a monitored parameter of drug delivery device (10). The Examiner alleges that analog-to-digital converter (140) of Elsberry et al. is "configured to generate a second signal based on a monitored parameter of *the sensor* to a first (10) and second device (16)." (Office Action at page

2.) However, sensor (130) of Elsberry et al. is not the claimed "device" since it does not receive and is not controlled by the first control signal. The alleged first control signal in Elsberry et al. is generated by processor (100) of device (10) and is received by device (10). Moreover, sensor (130) is not the same as or a part of drug delivery device (10). Rather, sensor (130) monitors nerve cell activity that may be used by microprocessor (100) to determine a drug dosage delivered by drug delivery device (10). (See Elsberry et al. at column 4, line 25 through column 5, line 65 and Fig. 2).

Moreover, no disclosure in Elsberry et al. teaches or suggests that analog-to-digital converter (140) of Elsberry et al. generates a control signal based on a monitored parameter of *device (10)*. Nevertheless, the Examiner asserts that "the second processor (140) a A-D converter receives a control signal (sensor output) from the sensor (130) and converts it to another control signal (modified sensor output) to which first processor (100) creates an output control signal which is used to run the drug pump in closed loop drug delivery (col 8, ln 10-20) (Figure 2)." (See Office Action at pages 5-6). The passage to which the Examiner refers simply states that "sensor 130 can be used with a closed loop feedback system in order to automatically determine the level of drug delivery necessary." (Col. 8, lines 12-15.) This passage, however, does not disclose or otherwise teach that analog-to-digital converter 140 generates a control signal based on a monitored parameter of device 10. In fact, this is not necessarily the case. A closed loop feedback system can be accomplished in many other ways. For example, closed loop operation of Elsberry et al. can be achieved by monitoring nerve cell responses to drug delivery and adjusting operation of drug delivery device (10) until

a desired nerve cell response is achieved. In this example, closed loop operation is based on monitored nerve responses to a drug and not a monitored parameter of device (10), as asserted by the Examiner.

Consequently, because Elsberry et al. fails to disclose or suggest every claim element of independent claim 50, or claims 51-60 and 62-107 that depend therefrom, the 35 U.S.C. § 102(b) rejection with respect to these claims is improper and should be withdrawn.

Furthermore, independent claim 142, from which claims 143-149 ultimately depend, recites a combination of elements including, among other things, a first processor connected to the sensor for processing the detected electrical signals to generate a first control signal; a device configured to receive the first control signal and be controlled by the first control signal; and a second processor configured to generate a second control signal based on a measured parameter of at least one of the detected electrical signals and the first control signal, the second processor configured to provide information relating to delivery of an agent to the body to a second device based on the second control signal. Elsberry et al. fails to disclose, at least, a second processor configured to provide information relating to delivery of an agent to the body to a second device based on the second control signal.

The Examiner asserts that sensor (130), microprocessor (100), device (10), analog-to-digital converter (140), and device (16) of the Elsberry et al. system respectively correspond to the claimed sensor, first processor, device, second processor, and second device recited in Applicants' independent claim 142. The

Examiner further asserts that the analog-to-digital converter (140) of Elsberry et al. is “configured to generate a second signal based on a monitored parameter of the sensor to a first (10) and second device (16) with processor (200) to provide information relating to delivery of an agent.” (Office Action at page 2.) Applicants respectfully disagree with the Examiner's assertion.

Elsberry et al. discloses that analog-to-digital converter (140) receives neural cell activity from sensor (130) and converts the monitored cell activity to a digital output signal. Based on the digital output signal of the analog-to-digital converter, microprocessor (200) of signal generator device (16) determines pulse parameters and delivers pulses of electric energy to a portion of a patient's body. (See Elsberry et al. at col. 8, line 18 though col. 9, line 27 and Fig. 5.) However, Elsberry et al. neither discloses nor suggests that analog-to-digital converter (140) provides information relating to *delivery of an agent to the body* to signal generator device (16). Instead, the analog-to-digital converter (140) of Elsberry et al. provides processed cell activity to microprocessor (200) of signal generator device (16), which uses the cell activity data to deliver electric energy to a portion of a patient's body.

In the Office Action, the Examiner further asserts that:

Regarding claim 142, Elsberry et al. discloses a second device (16) which is coupled to the sensor (130) for additional treatment in conjunction with the first device (10) in which the processor (100, 140, 200) are interconnected to each through the sensor and different control signals sent to the devices (10,16) and therefore are interrelated to each other (cols. 8-10) during treatment by either pre-programmed protocols or clinician access (Figure 2).

(Office Action at page 6). This assertion that all of the components are generally “interconnected” and “interrelated” does not specifically address where in Elsberry et al. the analog-to-digital converter (140) provides information relating to *delivery of an agent to the body* to signal generator device (16). The passages of Elsberry et al. cited by the Examiner fail to disclose or suggest that any of processors (100, 140, and 200) provides information related to *delivery of an agent to the body* to signal generator device (16). In fact, Elsberry et al. is altogether silent with respect to providing information related to delivery of an agent to the body to signal generator device (16), and does not disclose or suggest such a feature.

Consequently, because Elsberry et al. fails to disclose or suggest every claim element of independent claim 142, or claims 143-149 that depend therefrom, the 35 U.S.C. § 102(b) rejection with respect to these claims is improper and should be withdrawn.

Because Elsberry et al. fails to disclose or suggest every claim element of independent claims 50 and 142, or claims 51-60, 62-107 and 143-149 that depend therefrom, the 35 U.S.C. § 102(b) rejection of these claims is improper and should be withdrawn.

Applicants also note that that the Office Action groups a number of claims together in a common rejection, without specifically addressing certain features contained in one or more of the rejected claims. For example, claim 65, which depends from independent claim 50, is directed toward an embodiment of claim 50, “wherein the second control signal is used to display information for delivery of an agent.” Similarly,

claim 84, which depends from independent claim 50, is directed toward an embodiment of claim 50, "wherein the second processor is configured to transmit information relating the second control signal to a practitioner." The Office Action fails to cite any references that disclose these features. In fact, the Office Action has failed to address these claim elements altogether. Accordingly, Applicants respectfully submit that dependent claims 51-107 and 143-149 are in condition for allowance for, at least, their dependence from independent claims 50 and 142 and further in view of their additional recitations.

Applicants respectfully traverse the 35 U.S.C. § 103(a) rejections of claims 60, 86, 88, and 108. Each of these claims depends from independent claim 50. The secondary applied references do not remedy the deficiencies of Elsberry et al. described above. Accordingly, the 35 U.S.C. § 103(a) rejection of these claims is improper and should be withdrawn.

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

The Office Action contains a number of characterizations and assertions regarding the claims and the cited art with which Applicants do not necessarily agree. Unless expressly noted otherwise, Applicants decline to subscribe to any statement or characterization in the Office Action.

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Please grant any extensions of time required to enter this response and charge  
any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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Dated: October 30, 2007

By:

A handwritten signature in black ink, appearing to read 'Brad C. Rametta', written over a horizontal line.

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